# Predicting Reduction in Lost Productivity and Indirect Costs Among Patients With Atopic Dermatitis Treated With Ruxolitinib Cream

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## Introduction

- Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by itching, dryness, and redness[1]
- AD prevalence is approximately 10%–15% in children and 5%–10% in adults in the United States[2-4]
- Patients with AD, as well as caregivers, may incur substantial indirect costs based on missed days or lost productivity at work and reduced quality of life[5]
- Janus kinases (JAKs) play an important role in the pathogenesis of AD and the development of itch by mediating proinflammatory cytokines in skin and sensory neurons[6,7]
- Ruxolitinib cream is a topical selective inhibitor of JAK1 and JAK2 in development for the treatment of AD[8]
- In two 52-week phase 3 AD studies of identical design (TRuE-AD1 [NCT03745638] and TRuE-AD2 [NCT03745651]), ruxolitinib cream demonstrated anti-inflammatory activity, with rapid and sustained antipruritic action vs vehicle, and was well tolerated[8]
  - Patients applying ruxolitinib cream reported greater improvements in daily activities and work productivity using the Work Productivity and Activity Impairment (WPAI) questionnaire vs vehicle over 8 weeks of treatment[9]

## Objective

- To estimate the overall indirect costs due to workplace impairment associated with AD, based on data from phase 3 studies, in patients who applied ruxolitinib cream vs vehicle

## Methods

### *Phase 3 Study Design and Patients*

- Eligible patients were aged ≥12 years with AD for ≥2 years and had an Investigator's Global Assessment score of 2 or 3 and 3%–20% affected body surface area (excluding scalp)
- Key exclusion criteria were unstable course of AD, other types of eczema, immunocompromised status, use of AD systemic therapies during the washout period and during the study, use of AD topical therapies (except bland emollients) during the washout period and during the study, and any serious illness or medical condition that could interfere with study conduct, interpretation of data, or patients' well-being
- In the vehicle-controlled period of TRuE-AD1 and TRuE-AD2, patients were randomized (2:2:1) to 1 of 2 ruxolitinib cream strength regimens (0.75% twice daily [BID] or 1.5% BID) or vehicle cream BID for 8 weeks of double-blind treatment
  - Patients on ruxolitinib cream subsequently continued treatment for 44 weeks on intermittent therapy with ruxolitinib cream; patients initially randomized to vehicle were rerandomized 1:1 (blinded) at Week 8 to either ruxolitinib cream regimen

### *Assessments and Model Inputs*

- Overall work impairment was assessed using the WPAI Questionnaire–Specific Health Problem, version 2.0 (WPAI:SHP v2.0)[10] for all employed patients at Weeks 2, 4, and 8; scores are expressed as a percentage of impairment, with higher scores indicating more impairment
- WPAI overall work impairment scores were converted to an economic model of lost productivity using a human capital approach
- The proportion of time with impairment was combined with epidemiologic data on employment status among patients with AD[11] and median weekly hourly wage from the US Bureau of Labor Statistics[12] (**Table 1**)
- Indirect cost savings were applied to a hypothetical 1,000,000-member health plan to examine the societal perspective (**Table 1**)

**Table 1. Model Inputs**

| Characteristic | Input |
|---|---|
| Demographics | |
| Median age, y[8] | 32.0 |
| Female, %[8] | 61.7 |
| Employment status, %[11] | |
| Full time | 79 |
| Part time | 21 |
| Median weekly wage, $[12] | |
| Full time | |
| Male | 968 |
| Female | 843 |
| Part time | |
| Male | 375 |
| Female | 356 |
| Plan population funnel | |
| Plan size (assumption) | 1,000,000 |
| Proportion with diagnosed AD, %[13] | 0.82 |
| Proportion employed (full or part), %[11] | 54.5 |
| Receiving treatment, %[13] | 59.0 |

AD, atopic dermatitis.

## Results

### *Patients in the Phase 3 Studies*

- A total of 1249 patients (median age, 32 years) were randomized
- Distribution of baseline demographics and clinical characteristics was similar across treatment groups (**Table 2**)

**Table 2. Patient Demographics and Baseline Clinical Characteristics**

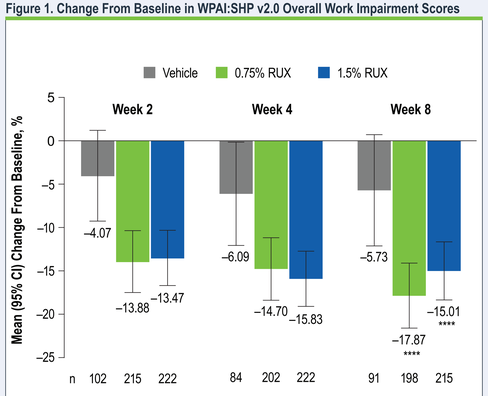
| Characteristic | Vehicle (n=250) | 0.75% RUX (n=500) | 1.5% RUX (n=499) | Total (N=1249) |
|---|---|---|---|---|
| Age, median (range), y | 34.0 (12–82) | 33.0 (12–85) | 31.0 (12–85) | 32.0 (12–85) |
| Female, n (%) | 159 (63.6) | 304 (60.8) | 308 (61.7) | 771 (61.7) |
| Race, n (%) | | | | |
| White | 170 (68.0) | 345 (69.0) | 355 (71.1) | 870 (69.7) |
| Black | 61 (24.4) | 118 (23.6) | 113 (22.6) | 292 (23.4) |
| Asian | 10 (4.0) | 16 (3.2) | 20 (4.0) | 46 (3.7) |
| Other | 9 (3.6) | 21 (4.2) | 11 (2.2) | 41 (3.3) |
| Region, n (%) | | | | |
| North America | 172 (68.8) | 342 (68.4) | 341 (68.3) | 855 (68.5) |
| Europe | 78 (31.2) | 158 (31.6) | 158 (31.7) | 394 (31.5) |
| BSA, mean (SD), % | 9.6 (5.5) | 10.0 (5.3) | 9.6 (5.3) | 9.8 (5.4) |
| EASI, mean (SD) | 7.8 (4.8) | 8.1 (4.9) | 7.8 (4.8) | 8.0 (4.8) |
| IGA, n (%) | | | | |
| 2 | 64 (25.6) | 125 (25.0) | 123 (24.6) | 312 (25.0) |
| 3 | 186 (74.4) | 375 (75.0) | 376 (75.4) | 937 (75.0) |
| Itch NRS score, mean (SD) | 5.1 (2.4) | 5.2 (2.4) | 5.1 (2.5) | 5.1 (2.4) |
| ≥4, n (%) | 159 (63.6) | 324 (64.8) | 315 (63.1) | 798 (63.9) |
| Duration of disease, median (range), y | 16.5 (0.8–79.1) | 15.1 (0.1–68.8) | 16.1 (0–69.2) | 15.8 (0–79.1) |
| Facial involvement, n (%)* | 93 (37.2) | 195 (39.0) | 197 (39.5) | 485 (38.8) |
| Number of flares in last 12 mo, mean (SD)* | 7.3 (25.7) | 5.2 (6.7) | 6.0 (17.6) | 5.9 (16.5) |

BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NRS, numerical rating scale; RUX, ruxolitinib cream.
* Patient reported.

### *Overall Work Impairment*

- Improvements in WPAI:SHP scores related to overall work impairment were observed at Weeks 2 and 4 for patients who applied either strength of ruxolitinib cream vs vehicle, with a significantly greater change from baseline with ruxolitinib cream vs vehicle at Week 8 (**Figure 1**)
- Overall work impairment scores for the model input are shown in **Table 3**

**Figure 1. Change From Baseline in WPAI:SHP v2.0 Overall Work Impairment Scores**




RUX, ruxolitinib cream; WPAI:SHP v2.0, Work Productivity and Activity Impairment Questionnaire–Specific Health Problem, version 2.0.
**** $P<0.0001$.

**Table 3. WPAI:SHP v2.0 Scores for Overall Work Impairment**

| WPAI:SHP v2.0 Score, mean | Vehicle (n=244) | 0.75% RUX (n=483) | 1.5% RUX (n=481) |
|---|---|---|---|
| Baseline | 36.4% | 33.6% | 31.8% |
| Week 2 | 32.4% | 18.0% | 17.8% |
| Week 4 | 29.4% | 16.8% | 14.7% |
| Week 6* | 30.2% | 15.6% | 15.1% |
| Week 8 | 31.0% | 14.3% | 15.5% |

RUX, ruxolitinib cream; WPAI:SHP v2.0, Work Productivity and Activity Impairment Questionnaire–Specific Health Problem, version 2.0.
* Average of Weeks 4 and 8.

### *Indirect Cost Model*

- Indirect costs were calculated from the WPAI scores for overall work impairment over the 8-week trial period for each treatment (**Table 4**)

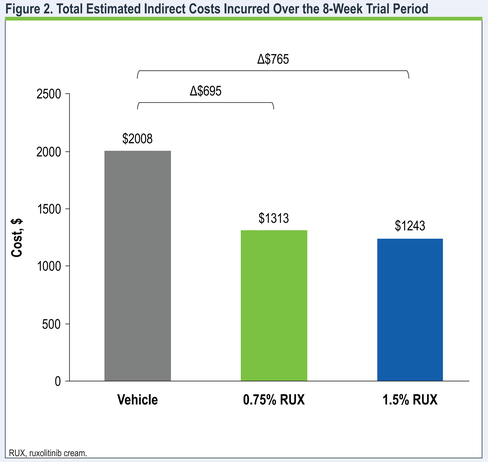
**Table 4. Estimated Indirect Costs Incurred per Treated Patient During the 8-Week Trial Period**

| Indirect Costs per Time Period | Vehicle | 0.75% RUX | 1.5% RUX |
|---|---|---|---|
| Weeks 0–2 | $569 | $525 | $497 |
| Weeks 2–4 | $507 | $281 | $280 |
| Weeks 4–6 | $460 | $263 | $230 |
| Weeks 6–8 | $472 | $243 | $236 |

RUX, ruxolitinib cream.

- The total estimated indirect costs over the 8-week period were lower for patients applying either strength of ruxolitinib cream vs patients applying vehicle (**Figure 2**)

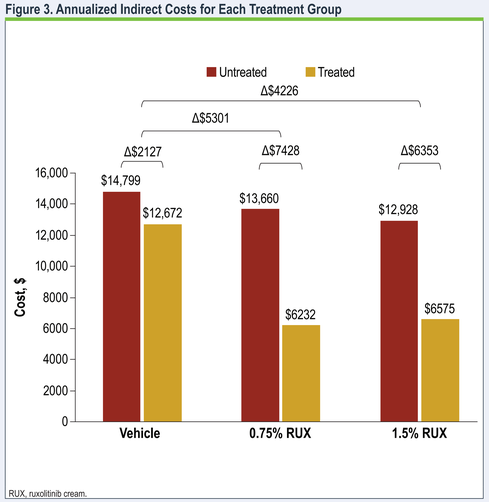
**Figure 2. Total Estimated Indirect Costs Incurred Over the 8-Week Trial Period**




RUX, ruxolitinib cream.

- Over a 1-year horizon, incremental indirect cost savings were estimated to be $5301 and $4226 for patients who used 0.75% or 1.5% ruxolitinib cream (**Figure 3**)

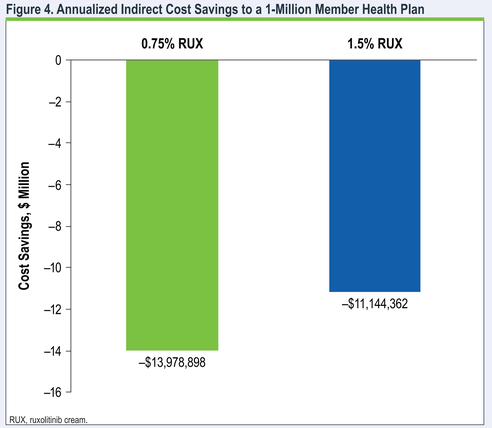
**Figure 3. Annualized Indirect Costs for Each Treatment Group**




RUX, ruxolitinib cream.

- Using the per-patient indirect cost savings amounts, the incremental annual indirect cost savings were estimated to be approximately $14 million and $11 million for a 1,000,000-member health plan if patients were treated with 0.75% ruxolitinib cream or 1.5% ruxolitinib cream, respectively, compared with vehicle (**Figure 4**)

**Figure 4. Annualized Indirect Cost Savings to a 1-Million Member Health Plan**




RUX, ruxolitinib cream.

## Conclusions

- **The economic model estimates that ruxolitinib cream may potentially reduce the annual indirect costs associated with an individual with AD, compared with vehicle**
- **Extrapolation of the findings to a 1 million-member health plan estimates that the reduction in indirect costs may be >$10 million per year**

### Disclosures

LB and KM-W are employees of Curta Inc. and served as paid consultants to Incyte Corporation in connection with this study. LFE has served as an investigator, consultant, speaker, or data safety monitoring board member for AbbVie, Almirall, Arcutis, Asana BioSciences, Dermavant, Eli Lilly, Forte Biosciences, Galderma, Ichnos/Glenmark, Incyte Corporation, Janssen, LEO Pharma, Novartis, Ortho Dermatologics, Otsuka, Pfizer, Regeneron, and Sanofi Genzyme. JIS has received honoraria for advisory board, speaker, and consultant services from AbbVie, Asana, Bluefin, Boehringer Ingelheim, Celgene, Dermavant, Dermira, Eli Lilly, Galderma, GlaxoSmithKline, Glenmark, Incyte Corporation, Kiniksa, LEO Pharma, Menlo, Novartis, Pfizer, Realm, Regeneron, and Sanofi; and research grants for investigator services from GlaxoSmithKline and Galderma. VNJ and JHL are employees and shareholders of Incyte Corporation. MEK was an employee and shareholder of Incyte Corporation at the time this analysis was conducted. SDS is an owner of VeriTech Corporation and served as a consultant to Incyte Corporation in connection with this study.

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### References

**1.** Langan SM, et al. *Lancet*. 2020;396(10247):345-360. **2.** Chiesa Fuxench ZC, et al. *J Invest Dermatol*. 2019;139(3):583-590. **3.** Silverberg JI and Simpson EL. *Dermatitis*. 2014;25(3):107-114. **4.** Silverberg JI, et al. *J Invest Dermatol*. 2015;135(1):56-66. **5.** Hebert AA, et al. *Curr Med Res Opin*. 2018;34(12):2177-2185. **6.** Bao L, et al. *JAKSTAT*. 2013;2(3):e24137. **7.** Oeljen LK, et al. *Cell*. 2017;171(1):217-228. **8.** Papp K, et al. *J Am Acad Dermatol*. 2021:doi:10.1016/j.jaad.2021.1004.1085. [Epub ahead of print]. **9.** Eichenfield LF, et al. Effects of ruxolitinib cream on work productivity and activity impairment in patients with atopic dermatitis: pooled results from two phase 3 studies. Presented at: American Academy of Dermatology Virtual Meeting Experience; April 23-25, 2021. **10.** Reilly MC, et al. *Pharmacoeconomics*. 1993;4(5):353-365. **11.** Andersen L, et al. *Br J Dermatol*. 2020;182(4):1007-1016. **12.** US Bureau of Labor Statistics. Usual weekly earnings of wage and salary workers. Available at: https://www.bls.gov/news.release/archives/wkyeng_01212021.htm. Accessed February 22, 2021. **13.** Clark R, et al. *J Med Econ*. 2018;21(8):770-777.